K040125

APR 1 9 2004

General Electric Medical Systems

Senographe Stereo
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**

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Date Prepared: January 16th, 2004

2. **Identification of Product:**

Device name	Senographe Stereo
Classification name	Mammographic X-ray system per 21CFR Section 892 1710
Manufacturer/ Distributor	General Electric Medical Systems 283, Rue de la Minière 78533 BUC Cedex France

3. **Marketed Devices**

Senographe Stereo is substantially equivalent to the device listed below:

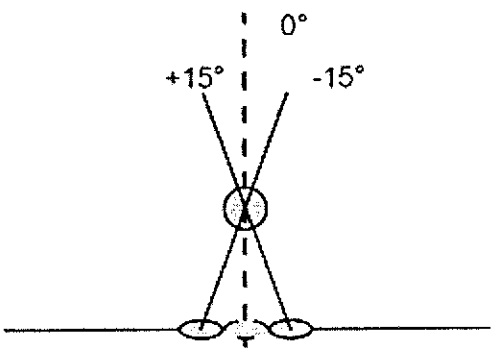
Model:	SenoVision
Manufacturer:	General Electric Medical Systems
510 (k):	K941191

4. **Device Description :**

SCIENTIFIC CONCEPT USED

If an image of the same object is taken with the tube arm at a different angle, the object appears to move along a line at right angles to the axis around which the

tube arm is rotated. The distance moved depends upon the tube arm angle, and is proportional to the height (Z) of the object above the image plane.



Senographe Stereo uses a stereo pair of images, taken with the tube arm angled to +15° and -15° with respect to the image receptor. The position of the three coordintates (X, Y, and Z) is computed using the position of the object indicated by the operator, on each of the two images and the known geometry of the system

DESCRIPTION OF THE DEVICE

Senographe Stereo is an option of Senographe DS composed of the following elements:

- A stereotactic positioner
- Display and stereo positioning software of the Senographe DS
- A lateral arm for the lateral approach procedures
- A vertical adapter for vertical approach procedures using a vacuum assisted device

1)- The stereotactic positioner

The stereotactic positioner is a device that attaches to Senographe DS by sliding onto the image receptor. There are two connectors in the back of this device that plug into the image receptor connectors. One of these connectors (which is common to the bucky) is used to energize the stereotactic positioner. The second connector is used to plug the stereotactic positioner to the gantry CAN bus through which the communication with the rest of the system is performed.
This positioner has the following functions:

- Compression: The breast is compressed between the compression paddle and the breast holding plate (made of carbon fiber) of the stereotactic positioner.
  This piece of equipment has its own manual compression system, independent to the compression of the Senographe DS, controlled with two compression

knobs, one at each side of the stereotactic positioner. The compression range of the stereotactic positioner is 10-100mm, with compression controlled manually.

- Needle positioning: The stereotactic positioner gets the (X,Y,Z) coordinates of the target area from the acquisition workstation. It provides two ways for reaching this position:
  - Manually by means of two sets of three knobs (one per X,Y and Z coordinate)
  - Motorized driven
- Safety features: the device has the following safety features:
  - A needle path lock: it ensures that all motorized motions are forbidden when the puncture tools is already in the breast
  - A luminous light turns red when the tip of the puncture tool is near the breast holder plate.

2) – The stereotactic software

The stereotactic software is a package that is activated only when the system is in stereotactic mode. The selection of the stereotactic mode is performed automatically upon hardware detection of the stereotactic positioner. In addition to the hardware detection, a software acknowledgment is provided through the CAN bus to confirm the selection.

The stereotactic software is a pre-installed package and consists of:

- A stereotaxy viewer on the acquisition workstation independent from the screening/diagnostic application.
- Exposure mode management.. Two exposure modes are provided: manual and one AOP (automatic optimization of parameters) modes..
- A software on the Senographe DS gantry to allow stereotactic motion control and specific interlocks to guarantee the safety during the stereotactic procedures, such as disabling all pre-set buttons.

3)– The lateral arm

The lateral arm is a mechanical accessory allowing the user to accede the lesion from both of the lateral sides of the stereotactic positioner. This device is basically the same as the one used on SenoVision. The only difference is the improvement of the sliding of the arm to enhance clinical effectiveness.

4) – The vertical adapter

The vertical adapter is a mechanical accessory used to install a vacuum assisted devices (such as a Mammotome, manufactured by Ethicon Endo Surgery).

HOW THE DEVICE WORKS

Senographe Stereo simply attached to Senographe DS by sliding onto the image receptor for fine needle aspiration, core biopsy, vacuum assisted biopsy or hook wire placement in upright or recumbent positions.

5. Indications for Use

Senographe Stereo is an optional accessory for the Senographe DS full field digital system. It is designed to allow the accurate location of lesions in the breast in three dimensions, using information extracted from steroetactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization, or treatment devices).

6. Comparison with Predicate Device

The GE Senographe Stereo is substantially equivalent to the following device:

SenoVision
Manufacturer: GE Medical Systems
510(k): K941191

Both of Senographe Stereo and SenoVision are Mammographic X-Ray System which aid in the performance of breast biopsies, presurgical localization.

7. Summary of Studies

Three kinds of tests have been performed to verify the Senographe Stereo:

- Functional test (Ref.#2363171_TDR_StereoPositioner_revB)
- Application accuracy test (Ref.#2398779-2 TDR revA)
- IQ Stereo test results (Ref.#2375268 TDR revB)

These tests prove the safety and effectiveness of Senographe Stereo.

8. Conclusions

The Senographe Stereo Principles of Operation, clinical effectiveness, Design, Construction and Materials are similar to existing marketed device. This system poses no added safety risk.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 9 2004

Larry Kroger, Ph.D.
Senior Regulatory Program Manager
GE Medical Systems, Inc.
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K040125
Trade/Device Name: Senographe Stereo
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: January 16, 2004
Received: January 20, 2004

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

Device name: Senographe Stereo

Indication For Use:

Senographe Stereo is an optional accessory for the Senographe DS full field digital system. It is designed to allow the accurate location of lesions in the breast in three dimensions, using information extracted from steroetactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization, or treatment devices).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040125